HFI-35 4/10/97 eff

DEPARTMENT OF HEALTH & HUMAN SERVICES

M 304N

Public Health Service
Food and Drug Administration

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

19900 MacArthur Blvd., Ste 300
Irvine, California 92715-2445
Telephone (714) 798-7600

WARNING LETTER

April 7, 1997 WL-21-7

Marvin Loeb
President
Trimedyne, Inc.
2801 Barranca Road
Irvine, CA 92714

Dear Mr. Loeb:

During an inspection of your manufacturing facility conducted between February 24 to March 20, 1997, our investigators determined that your firm manufactures holmium lasers intended for the treatment of patients. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, or storage are not in conformance with the Good Manufacturing Practice (GMP) for Medical Device Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish and control written manufacturing specifications and processing procedures to assure that the device conforms to its original design or any approved changes to that design [21 CFR 820.100]. For example, our investigation determined that your validation studies for your holmium laser did not contain sufficient evidence to provide a high degree of assurance that your manufacturing and processing procedures will consistently produce products which meet their pre-determined specifications and quality attributes as follows:

o tests and challenges were not repeated a sufficient number of times to assure reliable and meaningful results, testing was performed only once on one laser system;

o the ramp period for the energy stability studies was not clearly defined and the interval period used to determine energy stability was not defined;

o the energy stability results for the single pulse

operation failed to meet the established acceptance criteria and no justification was provided for accepting the results.

Tests and challenges should be repeated a sufficient number of times to assure reliable and meaningful results. All acceptance criteria must be met during the test or challenge. If any test or challenge shows that the equipment does not perform within its specifications, an evaluation should be performed to identify the cause of the failure. Corrections should be made and additional test runs performed to verify that the equipment performs within specifications.

Additionally, our investigation disclosed there was no written justification provided for the exclusion of test results involving pull strength tests performed in your validation studies for your crimping process of various fiber optics.

2. Failure to conduct and prepare written records of investigations, including conclusions and follow-up of devices which failed meet performance characteristics [21 CFR 820.162]. For example, our investigation determined that there w no documented investigation of the following malfunctions to your laser systems:

o nineteen lasers distributed with folding mirrors required replacement of the folding mirrors due to damage to the mirror and/or its retainer;

o four other reports involving low output error message, low coolant error message, a problem of the on-board power meter, and intracavity shutter failure resulting in replacement or adjustments of component parts to remedy the problems to these four lasers systems.

3. Failure to ensure that all complaints relative to the identity, quality, reliability, safety, or performance of a device are reviewed, evaluated, and maintained by a formally designated unit [21 CFR 820.198]. For example, our investigation disclosed 25 more or less reports received by your firm involving damaged folding mirrors were not evaluated and damage to the mirrors may result in attenuation of the beam.

Additionally, the above stated inspection revealed that your devices are misbranded within the meaning of section 502(t)(2) of the Act, in that your firm failed to submit information required by the Medical Device Reporting (MDR) regulation. Specifically, you failed to submit a MDR reports after receiving reports of information involving injuries to individuals from your laser systems.

This letter is not intended to be an all-inclusive list of deficiencies at your facility and/or with your devices. It is your responsibility to ensure adherence to each requirement of the Act

and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

We acknowledge that your firm has submitted to this office a response concerning our investigators observations noted on the form FDA 483. It appears that the response is adequate. Therefore no submissions for premarket clearance will be withheld for GMP reasons.

Whereas there are some technical issues involving the Performance Standard For Light Emitting Products and the requirements set forth in 21 CFR 812 involving the conduct of clinical investigations of devices, your response has also been forwarded to our Center For Devices and Radiological Health. This response and our information will be evaluated and communicated to you.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to seizure, injunction, and/or civil penalties.

Any correspondence concerning this matter should be addressed to:

Dannie E. Rowland
Compliance Officer
U.S. Food and Drug Administration
19900 MacArthur Boulevard
Irvine, California 92612-2445

Sincerely,

Mary J. Ayling

for Elaine C. Messa
District Director

cc: State Department of Public Health
Environmental Health Services
Attn: Chief Food and Drug Branch
714 "P" Street, Room 440
Sacramento, California 95814